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10/692,996	10/24/2003	Jay Prabhakar Gore	3220-73780	9342

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EXAMINER	
GAKH, YELENA G	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,996	GORE ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-69* is/are rejected.

7)☒ Claim(s) *1,6,8,25 and 42-49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/11/05, 08/07/06, 08/01/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Election of claims 1-69 filed on 07/20/07 is acknowledged. Claims 70-88 are cancelled without prejudice.

Information Disclosure Statement

2. The examiner respectfully requests the Applicants to indicate whether their confidential Technical Reports dated 2000 and 2001, provided in IDS filed on 04/11/05, were disclosed to the public and if they were, which were the dates of the disclosure.

Specification

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. All abbreviations in the specification should be accompanied with complete descriptions of the terms when they first mentioned, see e.g. "LRS" [lactated ringers solution] on page 8 (caption to Figure 1), "CFC" on page 9 (caption to Figure 19A), etc.

B. The equations (1)-(4) (pages 51, 55 and 58) contain typographic errors. For example, the second member of equation (1) should be $P_1IAR_{\lambda,1}$, rather than $P_1IAR^2_{\lambda,1}$. Equation (2) contains multiple typographic errors. Correction is required.

Equations (3) and (4) are not clear. The examiner respectfully requests the Applicants to provide exact equations and their explanation. At this moment it is not apparent, as to why the equations are not symmetrical relative to the second wavelength (equation (3)) or the second and the third wavelengths (equation (4)), respectively. The examiner also requests the Applicants to provide an explanation of a difference between equations (2) and (3), which supposedly describe quadratic calibration curves for two wavelengths. It is not clear, why they are different, and what the members of the equations stand for, e.g. why there are two different coefficients P_3 and P_4 for the same contribution $IAR^2_{\lambda,1}$. Also, it is not clear, if the calibration constants P_i have concentration measurement units.

Claim Objections

4. Claim 1 is objected to because of the following informalities: the last step (d) starts in the middle of the sentence. Claim 6 is objected to because of the following informalities: "cm-1" should be changed to "cm^{-1}". Claim 8 is objected to because it contains an extra expression: "The method of claim 1, wherein" in the middle of the claim, which is obviously a typo. It appears that claim 25 has the wrong dependency, since claim 22 does not have (a)-(e) steps. Appropriate corrections are required.

5. Claims 42-49 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite specific absorbance bands, which are inherently present in detected spectrum obtained by the method recited in the parent claim. Therefore they do not recite any further limitations to claim 28.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method, which is either based on known IR spectrum of the organic compound or comprises the step of obtaining the IR spectrum of the organic compound, and which also comprises the step of filtering out selected wavelength ranges before detecting the spectrum in order to obtain 'n-1' or less wavelength bands, does not reasonably provide enablement for the method, in which these steps are absent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. There is not way for any person of an ordinary skill in the art to detect n-1 IR wavebands for the organic compound if, first, its full IR spectrum is not known, and, second, if the wavebands that should not be detected are not

filtered out before detection takes place. This requirement for enablement of the instant method is unambiguously disclosed in the specification (see page 14).

Claims 1-3, 6-11, 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method, which comprises calibration step and using a reference compound or a reference value, does not reasonably provide enablement for the method, in which such steps are absent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. There is not way for any person of an ordinary skill in the art to measure an amount of an organic compound in a biological sample using the method recited in these claims, if no reference compound is used in IR analysis, or no reference value is utilized in the algorithms for determining the amount of the compound.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method, in which the mean-centered concentration of glucose C_g is preliminary obtained by an independent method, does not reasonably provide enablement for the method, in which C_g is not preliminary obtained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification specifically discloses the equations for obtaining calibration curves, in which mean-centered concentration C_g is preliminary obtained by an independent method.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of all independent claims is not quite clear. What does the expression, "wherein each of said wavelength regions substantially correspond to an *absorption band of said absorption spectrum*", mean? The absorption spectrum is comprised of absorption bands, so the expression "an absorption band of the absorption spectrum" appears to be a tautology. Is it supposed to be "an absorption band *of said organic compound*"?

From step (a) it is not apparent, as to how it is possible to detect only n-1 or less wavelengths bands, if the absorption spectrum comprises 'n' bands? It appears that essential steps of selective filtering the desired wavelengths to be detected are omitted from the claim, which renders it incomplete and indefinite.

The examiner also would like to indicate that it is conventional to say that an organic compound absorbs *at* certain wavelengths of IR spectrum. Such expressions as "infrared electromagnetic radiation influenced by said organic compound" (step (a) of claim 1) or "wavelength bands absorbed by said organic compounds" (e.g. claim 23) do not seem to be technically correct expressions. The organic compound absorbs not wavelength bands, but rather electromagnetic energy *at* certain wavelengths (wavelength bands). The examiner respectfully requests the Applicants to consider using more conventional language of the art when amending the claims.

Regarding step (b), it is not clear, whether this is an active method step. It does not seem that there is a separate step of generating "an electrical signal in response to detecting the intensity of said number of said selected wavelength bands", since such step should be inherent for any sensor that has a response upon detecting changes in electromagnetic radiation. The examiner does not understand, what step (b) actually recites and considers the step of generating the electrical signal an inherent feature of detecting electromagnetic radiation by the sensor.

Claim 4 is not apparent, as to which "reference wavelength band integrated absorbance value" is meant in the claim. Is this the reference wavelength from a reference compound? Is this a wavelength from the same organic compound? The expression is indefinite. It is also not clear, what is the "first wavelength band integrated absorbance value". It is "first" relative to what? The same is true for "second wavelength band integrated absorbance value" in claim 5.

Claims 6-8 reciting specific narrow ranges of the wavelengths are unclear and indefinite, since it is not apparent, as to how these wavelength ranges are related to the absorption spectrum of the organic compound, which may not have absorption bands within these wavelength ranges. Moreover, claim 6 recites two adjacent wavebands - it is not apparent if there are two separate maxima in these wavebands, and if there are - how can they belong to the same compound? However, if these wavebands belong to different compounds, it is not clear, if they have

overlapping signals. It appears that the total waveband from about 1095 to about 1075 cm^{-1} is being detected. Claims 9-26 have similar problems.

Claim 27 recites in step (a) "wherein said infrared electromagnetic radiation includes (i) one or more wavelength bands of said infrared electromagnetic radiation". It is not clear, which role the expression "of said infrared electromagnetic radiation" should play in this recitation. If the infrared electromagnetic radiation includes "one or more wavelength bands", which else bands these might be, if not "of said infrared electromagnetic radiation"? The examiner suggests removing the expression "of said infrared electromagnetic radiation" as not containing any information. It is [illegible] further not apparent, as to what "one or more reference wavelength bands, which are substantially not absorbed by said organic substance" might be. Are they "absorbed" by any other compound? They obviously reflect the presence of a compound. Is this a reference compound? Also, as the examiner indicated above, the wavelength bands are not absorbed by the compound. The examiner respectfully requests the Applicants to comply with a conventional language of the spectroscopic field.

Claim 28 appears to recite a contradictory subject matter. If the incident IR signal comprises wavelength in a measurement range from 7 to 11 microns (sic! the Applicants are reminded that they should be consistent with measurement units, and therefore microns should be transformed into inverse centimeters), it inherently comprises glucose absorbance bands, and therefore it is not apparent, as to what specifically subparagraph (b) recites. It is further unclear, as to which "reference band" claim 28 refers to - is this the reference band from a reference compound? It is also not clear, how "said incident signal is modulated", and how such modulation provides the grounds for determining the glucose level. The step of modulation does not have any apparent relation to the method recited in the claim. The term "a post-absorbance signal" is unclear. Is this a transmitted signal? The examiner respectfully requests the Applicants to explain the meaning of the term "post-absorbance signal".

From claim 34-36 it is not apparent, whether different embodiments comprising different ways of purification of the biological sample are recited in the claims, or these are just different degrees of the purification. It is not apparent, how different degrees of purification affect any steps of the recited method. The same is true for claims 37-39.

Claims 42-48 do no appear to recite any active steps. Claim 28 recites detecting a "post-absorbance" (transmitted? reflected? scattered?) signal - such signal should comprise all wavelengths that are obtained upon irradiation of the sample with IR incident light in the indicated range, and therefore inherently includes all wavelengths from all compounds contained in the sample. It does not appear that the recitations of the claims anyhow further limit the subject matter of the parent claim. In claim 42 it is not clear, how the spectrum can contain a relative absorbance band. What is the relative absorbance band? How can glucose absorbance band have a first relative absorbance band for an interfering substance potentially present in the sample? This expression does not make sense. Glucose absorbance band is the glucose absorbance band. The interfering compound can have an absorbance band that overlaps with the glucose absorbance band. The examiner is confused with the language of this and analogous claims.

In claim 50 it is not apparent, as to how it is possible to modulate "at least a part of the current, the voltage, or the frequency". It is possible to modulate current, voltage, or frequency, but not the part of these values. Claim 51 is unclear, as to where "the periodic insertion of an infrared blocking material" occurs, and what this blocking is. Is this an IR chopper?

It is not clear, what the second modulation technique recited in claims 52-55 is, and how it is related to the method of determining the level of glucose.

Claim 56 recites the limitation "the sample cell window", which does not have an antecedent basis, as no "cell window", or even "a sample cell" is recited in the parent claim.

Claims 57-69 have the same problems as those outlined for the preceding claims.

The examiner suggests reconsidering and amending the pending claims in order to clarify their subject matter. At present the examiner considers the pending claims unclear and indefinite, replete with technical errors and difficult to interpret.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claims 1-9, 11-27** are rejected under 35 U.S.C. 102(e) as being anticipated by Lillenfeld-Toal (US 6,484,044).

Lillenfeld-Toal teaches a method of measuring an amount of an organic substance (glucose) contained within a biological sample, the compound having an infrared absorption spectrum, which includes a set of wavelength regions (see Figure 3), the method comprising detecting a number of selected wavelength bands from the spectrum less than the total number of the wavebands of the compound: for example detecting at least three different wavelengths (col. 4, lines 1-2) of selected wavenumbers 1151, 1105, 1080, 1036 and 992 cm^{-1} (col. 4, line 15) (corresponding detecting in the regions recited in claims 6-8 and 14-16); generating an electrical signal in photoacoustic sensor (in piezoelectric transducer 6, col. 3, lines 44-45) in response to detecting the intensity of the bands at these wavenumbers; and processing said electrical signal with a quantification algorithm, e.g. "by a least square calculation referring to reference spectra such as shown in FIGS. 2 or 3 for known glucose concentrations. The calculated concentration is displayed on display 9. Alternatively, the glucose concentration could also be calculated from an average of concentrations obtained from the absorptions at each wavelength relative to reference absorption for a reference glucose concentration determined beforehand" (col. 4, lines 26-34) (claims 3-5). Equations recited in claims 19-22 are conventional equations for partial least square analysis with the number of contributions defined by the number of input wavelengths.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lillenfeld-Toal.

Regarding claims 10, while Lillenfeld-Toal does not specifically teach filtering the biological sample, it is a conventional procedure for invasive vs. non-invasive detection of glucose. Lillenfeld-Toal discloses the method for detecting glucose both in tissue (non-invasive) and in blood (invasive) (see Abstract), and therefore it would have been obvious for any person of ordinary skill in the art to filtrate the biological sample before IR spectroscopic measurements.

14. **Claims 28-69** are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Heise et al. (Appl. Spectr., 1994), Bhandare et al. (Appl. Spectr., 1994), Budinova et al. (Appl. Spectr., 1997), or Vonach et al. (Appl. Spectr., 1998) in view of Purdy et al. (US 5,460,177).

All references disclose a method of measuring a glucose level within a biological sample using mid-infrared spectroscopy by measuring a set of wavelength regions, in which glucose absorbs in mid-IR range: 1200-950 cm^{-1} (see e.g. Heise, page 88, left column) by obtaining a sample of a biological fluid, passing an incident signal of indicated wavelength through the sample, detecting a post-absorbance signals and calculating glucose concentration from said post-absorbance signal. All references disclose detecting glucose at specific wavelengths: "for glucose, the best predicting results were achieved within the rather narrow spectral range of 1200

to 950 cm^{-1}, where the most intensive absorption bands of aqueous glucose exist" (Heise, page 88, left column); Budínova discloses the following wave-numbers for glucose, which slightly differ from the ones recited in the claims: 1035, 1078, 1104 and 1148 cm^{-1} with the full range of 1185-950 cm^{-1}; Vonach indicates that "the spectral change [upon adding glucose] is in accordance with the glucose absorption with its maxima at 1038 and 1080 cm^{-1}" (page 821, left column).

Heise, Bhandare, Cadet, Budínova or Vonach do not specifically disclose modulating the incident signal upon irradiating the sample with mid-IR radiation. However, overheating the biological sample with intensive NIR or mid-IR radiation is a problem in analysis of component of biological sample, as discussed by Purdy.

Purdy indicates: "[c]ontinuous-spectrum noninvasive techniques make use of radiation in the near-infrared portion of the spectrum. However, in this portion of the spectrum, the absorption of radiation by water is very high. In addition, the concentrations of the analyte of interest in the bloodstream is typically low. As a result, the contribution of the analyte of interest to the signal intensity is only a relatively small change in the total signal intensity obtained by this technique. It has been found that detector noise is of the same order of magnitude as the change in intensity signal resulting from variations in analyte concentration. The variations in signal intensity as a result of variations in concentration of the analyte of interest are so small that, at intensities that have been used in the past, the detector's sensitivity may not be high enough to obtain sufficiently accurate readings. A possible solution to this problem would be to increase the intensity of the radiation incident on the body part of the subject. However, an increase in the intensity of incident radiation increases the amount of energy absorbed by the body part. Increases in the energy absorbed by the body part result in greater heating of the body part the amount of heat produced. Excessive heating can cause discomfort and even burns to the subject, which obviously would be undesirable. It is accordingly an object of this invention to provide a method for the continuous spectrum non-invasive spectroscopic detection of analytes in the bloodstream of living animals with increased signal-to-noise ratio" (col. 1, lines 64-67 and col. 2, lines 1-25).

Purdy provides a solution to the problem by using a chopper for periodically interrupting radiation emitted from the bulb, i.e. modulating intensity of the incident signal: "A method for

non-invasive detection of the concentration of an analyte in the blood of a living animal includes the steps of irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum; detecting the intensity of radiation emitted from the body part at a plurality of discrete wavelength ranges within the continuous spectrum; and using the detected intensity to calculate the concentration of the blood analyte" (col. 2, lines 31-39

It would have been obvious for any person of ordinary skill it the art to modulate intensity of the incident signal as taught by Purdy in any of Heise, Bhandare, Cadet, Budínova or Vonach's methods for the reasons analogous to the ones indicated by Purdy, i.e. in order to prevent overheating of the sensitive biological sample, because the analysis is performed by using radiation in thermal range (mid-IR frequencies).

While none of the specific references teaches filtrating the biological sample before performing measurements, it is a conventional step in most analytical spectroscopic studies of biological samples, as admitted by the Applicants (see page 24, paragraph [100]) and therefore it would have been obvious for any person of ordinary skill in the art to filtrate biological samples using ultrafiltration techniques well known in the art.

Since the measurement path is defined by penetration of the mid-IR incident radiation and therefore defined the output data, it would have been obvious for any person of ordinary skill in the art to optimize the penetration depth (measurement path) in order to obtain the most accurate results by comparing with the reference data.

Since dual modulation of the incident signal is recited in the claims 52-55 without any relevance to the performing the method of detecting glucose levels, the examiner is not able to perform a quality search on such unclear and indefinite terms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/6/2007

YELENA GAKH
PRIMARY EXAMINER